APPENDIX "A"

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 245—September Term, 1963.

(Argued January 9, 1964 Decided January 17, 1964.)

Docket No. 28498

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

—v.—

SIDNEY STEINSCHREIBER, doing business as SIDCATS LABORATORIES, JOHN P. CALISE, WESTCHESTER BLOOD SERVICE, INC.,

Defendants-Appellants.

Before:

LUMBARD, *Chief Judge,*

KAUFMAN and MARSHALL, *Circuit Judges.*

Appeal from judgments of conviction entered in the United States District Court for the Southern District of New York, Harold R. Tyler, Jr., *J.*, sitting without a jury.

Affirmed.

Appendix "A"

ALBERT J. GAYNOR, Assistant United States Attorney, New York, N. Y. (Robert M. Morgenthau, United States Attorney for the Southern District of New York, Richard A. Givens, Charles A. Stillman and Robert J. Geniesse, Assistant United States Attorneys, New York, N. Y., on the brief), *for appellee.*

ABRAHAM S. ROBINSON, New York, N. Y. (Emanuel Thebner and Herbert Alan Johnson, New York, N. Y., on the brief), *for defendant-appellant Sidney Stainschreiber.*

ALEXANDER DREIBAND, New York, N. Y. (Dreiband, Bleecker & Silberman, New York, N. Y., on the brief), *for defendants-appellants John P. Calise and Westchester Blood Service, Inc.*

PER CURIAM:

The judgments below are affirmed on the opinion of Judge Tyler, reported at 219 F. Supp. 373 (S. D. N. Y. 1963).

APPENDIX "B"

Indictment—62 Cr. 919

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

v.

SIDNEY STEINSCHREIBER, doing business as SIDCAPS LABORATORIES, JOHN P. CALISE, WESTCHESTER BLOOD SERVICE, INC., HAROLD H. FISHER, KEMWORTH LABORATORIES, INC., and NORMAN CAPPEL,

Defendants.

COUNT ONE

The Grand Jury charges:

1. From on or about the 1st day of January, 1960 up to and including date of the filing of this indictment, in the Southern District of New York and elsewhere, SIDNEY STEINSCHREIBER, doing business as SIDCAPS LABORATORIES, JOHN P. CALISE, WESTCHESTER BLOOD SERVICE, INC., HAROLD H. FISHER, KEMWORTH LABORATORIES, INC., and NORMAN CAPPEL, defendants, unlawfully, wilfully and knowingly, did combine, conspire, confederate and agree together and with each other and with others to the Grand Jury unknown, to commit offenses against the United States, to wit, to violate Section 262 of Title 42, United States Code.

Appendix "B"

2. It was a part of said conspiracy that defendants HAROLD H. FISHER, KEMWORTH LABORATORIES INC., and NORMAN CAPPEL would manufacture and prepare and cause to be manufactured and prepared a product analogous to a therapeutic serum and applicable to the prevention, treatment and cure of diseases and injuries of man, to wit, dried normal human plasma, a biological product derived from whole blood, at establishments that did not then hold any applicable license issued by the Secretary of the Department of Health, Education and Welfare as required by Section 262 of Title 42, United States Code.

3. It was further a part of said conspiracy that defendants JOHN F. CALISE and WESTCHESTER BLOOD SERVICE, INC. would furnish liquid human plasma for manufacturing dried plasma at KEMWORTH LABORATORIES INC., and would contribute to the cost of manufacturing and of supplies therefor.

4. It was further a part of said conspiracy that defendant SIDNEY STEINSCHREIBER, doing business as SIDCAPS LABORATORIES, would cause the plasma described in paragraph 2 of this count to be sent, carried, and brought for sale from the States of New Jersey and Pennsylvania into the State of New York, and from the State of New York into foreign countries, to wit, Cuba, Israel, and other countries to the Grand Jury unknown, although said plasma was not propagated or manufactured and prepared at an establishment holding an applicable license issued by the Secretary of Health, Education and Welfare as required by Section 262 of Title 42, United States Code.

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APPENDIX "C"

Excerpts From Steinschreiber Briefs

* * *

* * * The use of citrated whole blood, perfected in 1914, came into widespread use during the First World War (*Zimmerman & Howell, supra*, pp. 428, 431, R. 1345). The practical uses of dried and liquid human blood plasma were not in widespread application until 1940-1942, although some emergency use of human blood plasma had been made in the past decade. (See *N. Y. Chapter, American Red Cross, The Story of the Blood Donor Service*, p. 6; see also, R. 1305, Appendix, pp. 54a-55a.)

From the history of the use of blood plasma, we may conclude that Congress in 1902 had no intention of regulating the processing of either whole human blood, nor of normal human blood plasma. The learned District Judge inadvertently overlooked the historical facts outlined above when he imputed to Congress the intent to regulate blood plasma preparation in 1902 (see Opinion of Tyler, Jr., D. J. at Appendix p. 28a).

In the years between 1902 and 1944, a new product, normal human blood plasma, was introduced to the medical world (Appendix, pp. 54a, 55a, 60a-62a). Indeed, during the war years of 1940-1944, the use and urgent need for normal human blood plasma was widely known in the United States, and we must presume that Congressmen, as well as their fellow-citizens, were well aware of the importance of normal human blood plasma to the members of the armed forces who had been wounded in action. A glance at some statistics reflects that in January of 1944

the New York Chapter of the American Red Cross collected 39,400 pints of blood, and in March the Chapter collected 40,888 pints. In its Annual Report for the year 1943, the Public Health Service proclaimed the use of normal human blood plasma "* * * undoubtedly one of the greatest therapeutic agents of all time in emergency treatment" (H. R. Doc. 437, 78th Cong. 2nd Sess., 1943, p. 111).

It was in the midst of this nationwide effort to provide whole human blood and normal human blood plasma for the use of the armed forces, that Congress began its consideration of a proposed revision of the public health laws of the United States. The House Committee considering the revision and consolidation of the public health laws made certain changes "found necessary by long administrative practices," "the entire bill was carefully gone over," and then reported for consideration. 90 Cong. Rec. 4796 (1944) (Statement of Rep. Alfred D. Bulwinkle). Their comment upon the statute now in question is particularly revealing.

> Section 351, relating to the licensing of manufacturers of biologic products, would similarly be a reenactment of present law (42 U. S. C. 141-148) with only slight changes. The control would be extended to arsphenamine and other trivalent organic arsenic compounds, as has been done, though with less precision in appropriation acts. (H. R. Rept. 1364, 78th Cong., 2nd Sess. 1944).

No mention of human blood or human blood plasma! The only change that the Committee saw fit to recommend in this 1902 statute was the addition of another product

which it wished to bring within the licensing provisions of the new statute. Is it conceivable that Congress could have *forgotten* to consider normal human blood plasma? Is it not far more likely that while well aware of the contemporary use of normal human blood plasma, they felt that it was either too soon to license its production or that normal human blood plasma was *not* a biological product similar to the ones enumerated in the old statute, and that its regulation would require a new statute or a radical re-writing of the old statute? Does not the absence of any mention of whole human blood or its products present strongly persuasive evidence that this statute does *not* apply to normal human blood plasma, neither as enacted in 1902 nor as re-enacted in 1944? **(From pp. 4-6, Steinschreiber Brief)**

* * *

As discussed on pp. 1-3, *supra*, the 1944 re-enactment of the statute took place at a time when Congress would have been well aware of the use for blood plasma. Furthermore, Congress *did* change the statute to include a drug developed since 1902, a drug found particularly effective in the treatment and cure of a disease—syphilis. As noted by the Committee Report (pp. 2, 3), the drug inserted by the Committee was one which had previously been regulated under appropriation acts, presumably as an "analogous product." Despite the fact that the product was being regulated as an "analogous" product, Congress chose to make this regulation specific by including the article among the enumerated items **(From p. 12, Steinschreiber Brief)**.

* * *

Appendix "C"

The Government purports to find within Appropriation Acts and in the re-enactment of the 1902 statute, Congressional approval of the administration of the Biological Products Control Act, which administration, according to the Government, included the regulation of establishments engaged in the preparation and sale of normal human blood plasma.

If the Court will but look to the Appropriation Acts cited so conveniently by the Government on page 27 of its brief, it will find that these Acts contain *no* verbiage that supports the Government's contention of Congressional approval. As an example, the 1945 Appropriation Act, enacted two days before 42 U. S. C. 262, reads as follows:

> "National Institute of Health: * * * for regulating the propagation and sale of viruses, serums, toxins, and analogous products, including arsphenamine and other organic arsenic compounds analogous thereto; * * *" 58 Stat. 559.

In short, the Appropriation Act does indicate a Congressional intent in regard to arsphenamine, *but none whatsoever in regard to normal human blood plasma.* It is merely a recitation of the provisions of the Biological Products Control Act, as then in force, and lends absolutely no weight to the Government's position. It might be noted that the 1962 Appropriation Act, 75 Stat. 601, would be even less helpful to Government's attempt to bolster its case.

Apparently the Government finds no use for the Report of the Congressional Committee which considered the 1944 reenactment of the Biological Products Control Statute (quoted in full by appellant in his brief; p. 5). Is this not *the best evidence of Congressional intent in 1944?* **(From pp. 6, 7, Steinschreiber Reply Brief.)**

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